

EXHIBIT E

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

**IN RE: ETHICON, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY
LITIGATION**

**THIS DOCUMENT RELATES TO ALL
WAVE 1 CASES**

Master File No. 2:12-MD-02327

**JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE**

EXPERT REPORT OF DR. VLADIMIR IAKOVLEV

I. BACKGROUND

I am an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine, St. Michael's Hospital, Toronto, Canada. I hold an appointment at the Department of Laboratory Medicine and Pathobiology, University of Toronto. My professional activities include diagnostic examination of specimens surgically removed from human patients. These are larger excisions, smaller biopsies and cellular aspirations or smears. The organs and sites include genitourinary organs, gastrointestinal, head & neck, pulmonary, soft tissue and bone. My annual practice volume amounts to 3000-5000 cases. As a clinical physician, I provide clinical consultations to physicians at St. Michael's Hospital, which requires me to examine pathology specimens, review clinical information relating to the patient, and reach conclusions about the cause of a patient's injuries or illnesses. As an academic physician, I pursue research endeavors and teach medical students and residents. My academic activities also include tumor boards and teaching at CME workshops. I am also knowledgeable in the areas of chemistry, hematology, microbiology, serology, immunology and other special laboratory studies as they relate to my practice of pathology.

My pathology training was completed at the University of Manitoba Anatomical Pathology residency program, Canada. I hold medical licenses in the province of Ontario, Canada and in the State of Michigan, USA. As a pathologist with a subspecialty in anatomical pathology, I am a fellow of the Royal College of Physicians of Canada and a diplomate of the American Board of Pathology. For research training, I completed the Molecular Oncologic Fellowship Program at the Ontario

Effect on the tissue

Pain

Scar tissue inhabiting the mesh is not inanimate filler, but living tissue with vasculature, innervation, fluid and acid-base balance, and immune response. [56] [388] [464] [557] The tissue is subject to regular mechanisms of pain, out of which there are two main mechanisms for pain: direct irritation of nerve branches and irritation of receptors they supply.

Direct irritation of nerve branches can occur due to nerve entrapment with scar tissue within or encapsulating the mesh. [56] [216] [266] [274] [351] [509] [557] The nerves can also become distorted while growing through the mesh and can form traumatic neuroma, a tumor like nerve enlargements known for its painful nature. [274] [351] [509] The entrapped and distorted nerves are also at risk for additional pulling, compression and distortion forces due to the earlier described mesh-scar contraction and non-physiological attachments to the surrounding mobile tissues. Nerve involvement has been reported to exceed 60% for meshes excised for reasons of pain. [274] [56]

In regards to irritation of pain and other receptors the risks are due to specific factors: persistent chronic inflammation, fluid balance, blood supply, physical interlock within the mesh, and non-physiological attachments to mobile tissues. During our lifetime, we all experience the effect of inflammatory mediators causing hypersensitivity of pain and other (touch etc.) receptor. This leads to pain to touch or with movement, and if a stimulus is sufficiently high, it can cause pain at rest. [249] As discussed earlier, polypropylene meshes are invariably associated with a chronic inflammatory response, which creates the background capable to lower the pain sensitivity threshold.

Another specific factor within the mesh-scar complex is its compartmentalizing nature and attachments to the surrounding tissues. The ingrown tissue is in a vulnerable position for physical compression and distortion within the compartments of mesh pores and folds. The risk of compression can occur as a result of external forces, as well as from increased interstitial fluid pressure within the compartments. Externally, scar connection to the surrounding tissue leads to distortion and pulling during movements. Additionally, mesh shrinking during scar contraction leads to static tension within and between the attached tissues.

Sincerely,



Vladimir Iakovlev, MD, FRCPC, FCAP

DATE: January 29, 2016

FEEs

My billing rate is \$475/hr.

**LISTING OF CASES IN WHICH TESTIMONY HAS BEEN
GIVEN IN THE LAST FOUR YEARS**

Lisa Marie Fontes, et al. v. American Medical Systems, Inc.; 2:12-CV-02472

Debbie Jilovec, et al., v. American Medical Systems, Inc.; 2:12-CV-05561

Joann Serrano, v. American Medical Systems, Inc.; 2:12-CV-3719

Mary Weiler, et al. v. American Medical Systems, Inc.; 2:12-CV-05836

Carolyn F. Smothers v. Boston Scientific Corp. ; 2:12-cv-08016

Katherine L. Hall v. Boston Scientific Corp. ; 2:12-cv-08186

Julia Wilson v. Boston Scientific Corp. ; 2012-02626

Ronda Orozco, et al., v. Boston Scientific Corp. ; 2012-03068

Maria Cardenas v. Boston Scientific Corp. ; 2012-02912

Diane Albright v. Boston Scientific Corp. ; 2012-00909

Deborah Barba v. Boston Scientific Corp.